# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and WILLIAM P. DELANEY	) ) )
Plaintiffs, v.	) ) Civil Action No. 05-CV-10241 (MLW)
ELI LILLY AND COMPANY,	) )
Defendant.	) ) )

# AFFIDAVIT OF AARON M. LEVINE, ESQ. REGARDING AUTHENTICATION OF DOCUMENTS

- 1, Aaron M. Levine, declare under penalty of perjury that the following is true and correct:
- Attached as Appendix 1 is a true copy of the Scheduling Order in this case, dated April 22, 2005.
- 2. Attached as Appendix 2 is a true copy of pages 1-4 and the affirmation from Defendant Eli Lilly's Responses to Plaintiffs' First Set of Interrogatories, dated July 29, 2004.
- 3. Attached as Appendix 3 is a true copy of Defendant Eli Lilly and Company's Initial Disclosure Statement, dated May 6, 2005..
- 4. Attached as Appendix 4 is a true copy of pages 1-3 of Plaintiff Julie Delancy's Answers to Defendant's First Interrogatories, dated June 9, 2004.
- 5. Attached as Appendix 5 is a true copy of selected pages from the <u>Drug Topics Red Book</u>, Walter Cousins, ed., 1969.
- 6. Attached as Appendix 6 is a true copy of <u>In re Complex DES Litigation</u>, No. 830109 (Cal. Sup. Ct. Jul. 29, 1988).

7. Attached as Appendix 7 is a true copy of selected pages from the New York DES market share matrix.

I declare under penalty of perjury that the foregoing is true and correct.

Aaron M. Levine

Dated: December 4, 2006

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# Appendix 1

Scheduling Order in Delaney v. Eli Lilly and Co.

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### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

<u>JULIE DELANEY et al</u>

Plaintiff(s)

 $\nabla$ .

CIVIL ACTION
NO. 05-10241-MLW

ELI LILLY

Defendant(s)

### SCHEDULING ORDER

WOLF, D.J.

This case is governed procedurally by the 1992 Amendments to the Local Rules of the United States District Court for the District of Massachusetts (the "Local Rules"), which implement the District's Civil Justice Expense and Delay Reduction Plan. Counsel must, therefore, comply with the relevant Local Rules in the litigation of this case.

It is hereby ORDERED pursuant to Fed. R. Civ. P. 16(b) and Local Rule  $16\langle f \rangle$  that:

- [X] 1. Any Motion to Amend the pleadings, or any Motion to File additional pleadings, shall be filed by MAY 27, 2005, and responses shall be filed as required by the applicable provisions of the Federal Rules of Civil Procedure.
- [X] 2. The parties shall by MAY 6, 2005 make the automatic document disclosure required by Local Rule 26.2(A) and, if applicable, disclose the information required by Local Rule 35.1
- [X] 3. The parties shall by MAY 6, 2005 make the disclosure authorized by Local Rule 26.1(B)(1) and (2).
- [] 4. Discovery shall initially be limited to the issue(s) of The Statute of Limitations Defense and Product Identification, including, the deposition of the plaintiff, her mother, the pharmacist and the treating physician, and shall be complete by SEPTEMBER 30, 2005.

Case 1:05-cv-10241-MI W Document24 LEiled 04/22/2005 Lp Prop 2-af2, a schedule for filing motions for summary judgment will be established at this conference.

All provisions and deadlines contained in this Order having been established with the participation of the parties to this case, any requests for modification must be presented to the judge or magistrate judge, if referred for case management proceedings. Any requests for extension will be granted only for good cause shown supported by affidavits, other evidentiary materials, or reference to pertinent portions of the record. The request shall be made by motion and shall contain the reasons for the request, a summary of the discovery which remains to be taken, and a date certain when the requesting party will complete the additional discovery.

Counsel are encouraged to seek an early resolution of this matter. Additional case management conferences may be scheduled by the Court or upon the request of counsel.

> By the Court, DENNIS P. O'LEARY

April 22, 2005 Date

/s/ Dennis O'Leary Deputy Clerk

# Appendix 2

Selection from Defendant's Responses to Plaintiff's First Interrogatories

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

JULIE DELANEY, et al.,

Plaintiffs,

VS.

Civil Action No. 04-0349(ESH/AK)

ELI LILLY AND COMPANY,

Defendant.

# DEFENDANT ELI LILLY AND COMPANY'S RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES AND FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND/OR TANGIBLE THINGS

COMES NOW defendant Eli Lilly and Company (hereinafter "Lilly"), by and through its attorneys, Foley Hoag, LLP, pursuant to Rules 33 and 34 of the Federal Rules of Civil Procedure, and provides the following responses to Plaintiffs' First Set of Interrogatories and First Request for Production of Documents and/or Tangible Things to Defendant Eli Lilly and Company.

### PRELIMINARY STATEMENT

As a preface to each and every response to plaintiffs' interrogatories and requests, Lilly qualifies its response by stating that Lilly has not completed its investigation of the facts relating to this case, has not completed its discovery in this action and has not completed its preparation for trial. Lilly reserves the right to amend or supplement these responses as discovery in the case progresses, as new facts are developed and as new information is obtained. Therefore, the following responses are given without prejudice to Lilly's right to produce any additional evidence at trial or in connection with any pretrial proceeding.

Some of the events relevant to this action occurred over sixty (60) years ago. Due to the lapse of time, many of the individuals having personal knowledge of these events are

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deceased or otherwise unavailable and many of Lilly's documents are no longer available. As a consequence, Lilly's responses to these interrogatories and requests are necessarily limited by, and subject to, these qualifications.

The term diethylstilbestrol, as used in these responses, refers only to diethylstilbestrol. It does not refer to any chemically similar synthetic estrogen-like substance or to any congener of diethylstilbestrol.

# GENERAL OBJECTIONS

OBJECTION A: Lilly objects to these interrogatories insofar as they seek information for time periods beyond August 3, 1970, the date of birth for plaintiff Julie Delaney, on the grounds that such information is not relevant to any issue in this lawsuit and would not lead to the discovery of admissible evidence. It is apparent that no action by Lilly, its employees or any other person subsequent to that date could have any effect upon plaintiff Julie Delaney's alleged exposure to diethylstilbestrol.

OBJECTION B: Lilly objects to these interrogatories to the extent they seek information unrelated to the use of diethylstilbestrol for the prevention of certain accidents of pregnancy. The prescription drug, diethylstilbestrol, was approved by the Food and Drug Administration (FDA) for a variety of human uses other than use as an aid in the prevention of certain accidents of pregnancy. These indications did not involve the use of diethylstilbestrol in pregnant women, the only use that plaintiffs allege in their complaint and the only use relevant to this action. Accordingly, information concerning other uses for diethylstilbestrol is irrelevant and has no bearing upon the issues in this case nor is discovery into those uses reasonably calculated to lead to the discovery of evidence admissible at trial.

OBJECTION C: Lilly objects to these interrogatories to the extent they seek information concerning the manufacture, distribution or sale of diethylstilbestrol in sizes and

forms other than 5 and 25mg oral dosage forms, on the grounds that information concerning dosage sizes other than those indicated for use in prevention of accidents of pregnancy is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION D: Lilly objects to these interrogatories to the extent they seek information relating to injuries or adverse effects other than those alleged by plaintiffs on the grounds that such information is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION E: Lilly objects to these interrogatories to the extent they seek information protected by the attorney-client and/or the attorney work product privilege.

OBJECTION F: Lilly objects to these interrogatories to the extent that they are irrelevant and not reasonably calculated to lead to the discovery of admissible evidence.

OBJECTION G: Lilly objects to these interrogatories and definitions on the grounds that they are vague and overbroad to the extent they may exceed the scope of discovery allowed pursuant to the Federal Rules of Civil Procedure.

### **INTERROGATORIES**

### 1. Non-Lilly Contention

Do you contend that Plaintiff Julie Delaney was not exposed to the Lilly brand of diethylstilbestrol ("DES")? If so, state the factual basis of your contention.

RESPONSE: Lilly incorporates herein its objections E and G. Lilly further objects to this interrogatory as an improper attempt by plaintiffs to require Lilly to prepare plaintiffs' case. Lilly further states that plaintiffs have the burden of proving the facts necessary to establish the elements of their alleged cause of action, including the cause of any alleged injuries. Without waiving and subject to its objections, Lilly states that it has not completed its investigation and discovery in this matter, and cannot fully respond to this interrogatory at this

time. Because such information is not within the direct knowledge of Lilly, Lilly can only respond to the extent that the information is obtained through discovery, which is still ongoing. However, documents such as the *American Druggist Blue Book* and the *Drug Topics Red Book* show that many manufacturers had DES available for purchase by Hingham, Massachusetts pharmacies in 1970. The fact that many manufacturers' DES was available for purchase by pharmacies in Hingham, Massachusetts in the relevant time period is evidence that the DES allegedly taken by Plaintiff's mother, prior to her birth, could have been manufactured and sold by companies other than Lilly. Lilly's attorneys are currently investigating this issue and this answer will be supplemented if information responsive to this interrogatory is discovered. At the present time, the witnesses identified by plaintiffs may have information concerning the manufacturer(s) of any medications plaintiff's mother allegedly ingested during her pregnancy with plaintiff.

### 2. Witness for Non-Lilly Contention

Identify each and every individual(s) known to you, your attorneys or investigators, who may have any information concerning the identity of the brand of DES as set forth above.

RESPONSE: Lilly incorporates herein its response to Interrogatory No. 1.

### 3. White Cross Score

Do you contend that in the year of exposure as set forth in the Complaint, any manufacturer other than you, bottled or distributed DES in the dosage sizes indicated for use in prevention of accidents of pregnancy, as a round, white cross-scored non-imprinted tablet? If your answer is yes, identify the product or the manufacturer and any documents (by date, description or custodian), upon which you rely in making this statement. For your information, it

...... A use see of microgardites and rust request for fromchon of Documents and/or Tangible Things to Defendant Eli Lilly and Company but that many of the facts set forth in such others within the employ of Eli Lilly and Company at his direction, as to which facts he is informed and believes the same to be true and that the remaining facts are known by him to be Responses are not within his personal knowledge, having been assembled and compiled by

Subscribed and sworn to before me this 29th day of July, 2004.

true.

Jean C. Ballinger, Notary Public Resident of Marion County, IN

My Commission Expires: 01/05/09

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# Appendix 3

Defendant's Initial Disclosure Statement

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and WILLIAM P. DELANEY

Plaintiffs.

v.

CIVIL ACTION No. 05-CV-10241 (MLW)

Filed 12/05/2006

ELI LILLY AND COMPANY,

Defendant.

## DEFENDANT ELI LILLY AND COMPANY'S INITIAL DISCLOSURE STATEMENT

Defendant Eli Lilly and Company ("Lilly") makes the following initial disclosure pursuant to Fed. R. Civ. P. 26(a)(1) based upon the information reasonably available to Lilly at this time. Lilly respectfully reserves the right to amend or supplement this disclosure.

### PRELIMINARY STATEMENT

Some of the events relevant to this action occurred more than sixty (60) years ago. Due to the lapse of time, many of the individuals having personal knowledge of such events are deceased or otherwise unavailable and many of Lilly's documents are no longer available. As a consequence, the information contained in Lilly's Initial Disclosure Statement is necessarily limited by, and subject to, these qualifications.

Lilly reserves the right to object to the admissibility of any information contained in this Initial Disclosure Statement. Further, Lilly's disclosures are limited to information prior to the date of plaintiff's birth.

### ĭ. Rule 26(a)(1)(A) - People Likely to Have Discoverable Information

The following individuals are likely to have discoverable information that Lilly may use to support its claims or defenses:

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- Individuals identified in plaintiff's Complaint and other materials provided by A. plaintiff, including, but not limited to:
  - 1. Julie Lee Delancy Plaintiff's allegations and conditions 118 Walnut Street Middleboro, MA 02346
  - 2. William P. Delaney (plaintiff's husband) Plaintiff's allegations and conditions 118 Walnut Street Middleboro, MA 02346
  - 3. Barbara Ann O'Leary (plaintiff's mother) Plaintiff's allegations and conditions as well as her own conditions 68 Mandalay Road South Weymouth, MA 02190
  - 4 Leo Francis O'Leary (plaintiff's father) Plaintiff's allegations and conditions as well as his wife's conditions 68 Mandalay Road South Weymouth, MA 02190
  - 5. Daniel Schust, M.D. (plaintiff's treating physician) Conditions and treatment of plaintiff Department of Obstetrics and Gynecology Division of Reproductive Medicine Brigham and Women's Hospital 75 Francis Street Boston, MA 02115
  - б. Martha Ehrmann, M.D. (plaintiff's treating physician) Conditions and treatment of plaintiff South Shore Women's Health 851 Main Street, Suite 19 Weymouth, MA 02190
  - 7. Darlyne Johnson, M.D. (plaintiff's treating physician) Conditions and treatment of plaintiff South Shore Women's Health 851 Main Street, Suite 19 Weymouth, MA 02190
  - 8. Deborah Wooten, M.D. (plaintiff's treating physician) Conditions and treatment of plaintiff 201 River Street Norwell, MA 02061

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- Rachel Ashby, M.D. (plaintiff's treating physician)
   Conditions and treatment of plaintiff
   Department of Obstetrics and Gynecology
   Division of Reproductive Medicine
   Brigham and Women's Hospital
   75 Francis Street
   Boston, MA 02115
- Rafik Mansour, M.D. (plaintiff's treating physician)
   Conditions and treatment of plaintiff
   Boston Health Care for Women
   500 Brookline Ave., Suite A
   Boston, MA 02115
- Elena Yanushpolsky, M.D. (plaintiff's treating physician)
   Conditions and treatment of plaintiff
   Department of Obstetrics and Gynecology
   Division of Reproductive Medicine
   Brigham and Women's Hospital
   75 Francis Street
   Boston, MA 02115
   617-732-4648
- Dr. Patricia McShane (plaintiff's medical expert)
   Causation
   P.O. Box 9
   Lexington, MA 02420-0001
   800-858-4832
- B. Individuals identified by Lilly as experts on causation, state of the art, epidemiology, and efficacy:
  - A. Brian Little, M.D.
     State of the Art/ Efficacy
     Department of Obstetrics and Gynecology
     UMDNJ- New Jersey Medical School
     185 South Orange Avenue
     MSB E506
     Newark, NJ 07103
     973-972-4127
  - Eugene D. Albrecht, Ph.D.
     Reproductive Endocrinologist on Efficacy
     Department of Obstetrics and Reproductive Systems
     University of Maryland School of Medicine
     Bressler Research Laboratories, 11-017

     655 West Baltimore Street

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Baltimore, MD 21201 410-706-3391

- 3. Richard E. Blackwell, Ph.D., M.D.

  Reproductive Endocrinologist on Causation
  Professor of Obstetrics and Gynecology
  UAB School of Medicine
  Department of Obstetrics and Gynecology
  555 Old Hillman Building
  618 20th Street South
  Birmingham, AL 35249-7333
  205-934-6090
- Karin E. Michels, Sc.D.
   Epidemiology
   Assistant Professor of Obstetrics, Gynecology and Reproductive Biology
   Harvard Medical School
   Obstetrics and Gynecology Epidemiology Center
   221 Longwood Avenue
   Boston, MA 02115
   617-732-8496
- C. Don Carlos Hines, M.D. (Deceased)
   Safety, Efficacy, Testing, FDA, NDA, and Lilly Factual Information relating to diethylstilbestrol
   (By prior testimony; transcripts of Dr. Hines' testimony are available.)
- D. Edith M. Potter, M.D. (Deceased)
   Safety and Efficacy of diethylstilbestrol
   Non-Lilly Employee
   (By prior testimony; transcripts of Dr. Potter's testimony are available.)
- E. Theodore G. Klumpp, M.D. (Deceased)
   FDA matters relating to diethylstilbestrol
   Non-Lilly Employee
   (By prior testimony; transcripts of Dr. Klumpp's testimony are available.)
- F. Lilly Employee(s) or Former Employee(s) in sales area who may become relevant as facts are developed. To be determined.

This list is based upon the allegations contained in plaintiff's Complaint and on plaintiff's written discovery responses. Lilly anticipates that discovery into plaintiff's allegations may reveal additional individuals likely to possess discoverable information that Lilly may use to

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support its claims or defenses. Lilly will supplement this list to the extent necessary if additional individuals likely to possess discoverable information are identified.

### II. Rule 26(a)(1)(B) – Relevant Documents and Tangible Things

Lilly has made available to plaintiff's attorneys, in DES litigation unrelated to this case, a copy of relevant documents and tangible things in Lilly's possession, including Lilly's New Drug Application files for diethylstilbestrol, Lilly's product literature files for diethylstilbestrol, and certain correspondence that Lilly has identified as exhibits in other DES cases.

Lilly anticipates that discovery into plaintiff's allegations may reveal additional information or plaintiff may have specific requests for documents or tangible things. Lilly expects that documents relevant to this action will include medical records from plaintiff, spouse and mother, and documents and tangible things listed in plaintiff's Initial Disclosure Statement. Lilly reserves the right to update this list as additional information becomes available or is requested by plaintiff.

# III. Rule 26(a)(1)(C) - Computation of Damages Not applicable.

## IV. Rule 26(a)(1)(D) – Insurance Information

Lilly states that the issues surrounding Lilly's insurance coverage for diethylstilbestrol claims are complex. Because of disputes over possible insurance coverage, Lilly filed a lawsuit against certain insurance carriers who Lilly claimed had responsibility to provide coverage for certain diethylstilbestrol claims. This lawsuit resulted in several decisions, including opinions of the United States Court of Appeals for the District of Columbia, 794 F.2d 710 (D.C. 1986), and the Indiana Supreme Court, 482 N.E.2d 467 (Ind. 1985).

The litigation between Lilly and its insurers has been settled. The terms and conditions of the settlement agreement are confidential. The parties to the litigation, including Lilly, are

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precluded from disclosing the agreement or its contents by an order entered on November 18, 1987, by the United States District Court for the District of Columbia.

Lilly further states that it has currently available sufficient unencumbered assets to pay the damages alleged by plaintiffs in this action.

This disclosure is based on information reasonably available to Lilly as of the date of this disclosure. In making this disclosure, Lilly does not represent that it is identifying every individual, document, or tangible thing upon which it may rely to support its claims or defenses, nor does Lilly waive its right to object to production or to the use in this proceeding of any document or tangible thing on the basis of any privilege, the work product doctrine, relevancy, undue burden, competency, materiality, hearsay or any other valid objection. Rather, Lilly's disclosure represents its good faith effort to identify information as required by Fed. R. Civ. P. 26(a)(1).

Respectfully submitted,

ELI LILLY AND COMPANY

By Its Attorneys,

James J. Dillon (BBO # 124660)

Brian L. Henninger (BBO # 657926)

FOLEY HOAG LLP

155 Seaport Boulevard

Boston, MA 02111-2600

617-832-1000

Dated: May 6, 2005

### CERTIFICATE OF SERVICE

I certify that a true copy of the foregoing Initial Disclosure Statement was served on May 6, 2005 by .pdf file via electronic mail, upon:

Aaron M. Levine, Esq. Aaron M. Levine and Associates 1320 19<sup>th</sup> Street, N.W., Suite 500 Washington, D.C. 20036 Attorneys for Plaintiffs

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# Appendix 4

Selection from Plaintiff's Answers to Defendant's First Interrogatories

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

JULIE DELANEY and WILLIAM P. DELANEY	] ]
Plaintiffs,	
v.	CIVIL ACTION No. 04-CV-00349 (ESH)
ELI LILLY AND COMPANY,	]
Defendant.	] ]

# PLAINTIFF JULIE DELANEY'S ANSWERS TO DEFENDANT ELI LILLY AND COMPANY'S FIRST SET OF INTERROGATORIES

1. Please state your full legal name, your social security number and your date and place of birth, including the name and address of the hospital at which you were born, if any. If you have ever been known by any other name or names, please state each such name and where and when such other name was used.

ANSWER: a. Julie Lee Delaney

b. SSN: 015-62-8321

c. DOB: 8/3/70

- d. Quincy City Hospital, 114 Whitwell Street, Quincy, MA 02169
- e. Julie Lee O'Leary (1970 1997) Julie Lee Delaney (1997 - present)
- 2. Please state your present residential address and all former residential addresses and the inclusive dates for each.

ANSWER: a. 118 Walnut Street Middleboro, MA 02346 (2000 - present)

> b. 48 Russell Road Weymouth, MA 02190

3. Please state your marital status. If married, please state your spouse's full legal name, his residential address and the date of your marriage. If formerly married, for each spouse, please state his full legal name, his present residential address, the date of your marriage, the date of its termination, and the method by which it was terminated (e.g., annulment, divorce, death of spouse).

ANSWER:

- a. Married
- b. William Paul Delaney
- c. Address: 118 Walnut Street, Middleboro, MA 02346
- d. Date of Marriage: 3/15/97
- 4. Please state the full legal name of each of your parents, including your mother's maiden name, their places and dates of birth and their current residential address or addresses. If either of your parents is deceased, please state the date, place and cause of death.

ANSWER: a.

- Mother: Barbara Ann O'Leary
  - i. Barbara Ann Kuja
  - ii. DOB: 7/1/29
  - iii. Place of Birth: Quincy, MA
  - iv. Address: 68 Mandalay Road, South Weymouth, MA 02190
- b. Father: Leo Francis O'Leary
  - i. DOB: 11/26/30
  - ii. Place of Birth: Boston, MA
  - iii. Address: 68 Mandalay Road, South Weymouth, MA 02190
- 5. Please state the address of each residence of your mother for the period beginning five years prior to the date of birth of your mother's first child through the present.

### ANSWER:

- 50 Shawmut Street Quincy, MA 02169 (Previously)
- 7 Belmont Street
   Wollaston, MA 02171
   (1958 1963)
- c. 223 Ralph Talbot Street South Weymouth, MA 02190 (1963 - 1970)
- d. 68 Mandalay Road South Weymouth, MA 02190 (1970 - present)
- 6. If you contend that your mother took diethylstilbestrol ("DES" or "stilbestrol") during her pregnancy with you, please state the name and address of each physician who prescribed it; if any physician who prescribed DES is deceased, please state the name and address of the current custodian of his or her medical records; and please state the purpose for which the drug was prescribed.

### ANSWER:

- a. Quincy OB-GYN, including Drs. Carey, McKeogh, Sullivan, Cotter and Doyle
- b. Address: 30 Beach Street, Quincy, MA 02170
- c. Quincy OB-GYN is the current custodian of medical records.
- d. Stilbestrol prescribed to prevent miscarriage.
- 7. Please identify, by name and address, each pharmacy or other supplier that dispensed the DES allegedly ingested by your mother while pregnant with you. If you do not know the name of the pharmacy, please state the name and address of each pharmacy or retail drug outlet that was patronized by your mother or father during the twelve months that preceded your birth.

ANSWER: Plaintiff's mother's recollection is that she purchased the DES in Hingham, MA.

Plaintiff reserves the right to supplement this answer as discovery progresses.

Describe in detail the physical appearance of the diethylstilbestrol you allege your mother ingested, including its form (for example, pill, injection, capsule), the shape, color, or size of any pill, tablet or capsule, the dosage of the DES your mother took, and any markings that may have appeared on the product.

preparation with declarant.

I SOLEMNLY DECLARE AND AFFIRM UNDER THE PENALTY OF PERJURY THAT THE INFORMATION CONTAINED IN THE FOREGOING ANSWERS TO INTERROGATORIES ARE TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE.

AARON M. LEVINE & ASSOCIATES

Aaron M. Levine, #7864 1320 19th Street, N.W.

Suite 500

Washington, D.C. 20036

(202) 833-8040

Attorney for Plaintiff

# CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this day of June, 2004, a true and correct copy of the foregoing Plaintiff Julie Delaney's Answers to Defendant Eli Lilly and Company's First Set of Interrogatories was served via first class, postage prepaid, U.S. Mail, on counsel for Defendant:

James J. Dillon, Esq. FOLEY HOAG LLP 155 Seaport Boulevard Boston, MA 02210-2600

Lawrence H. Martin, Esq. FOLEY HOAG LLP 1875 K Street, N.W. Suite 800 Washington, D.C. 20006

Aaron M. Levine

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# Appendix 5

Selection from the <u>Drug Topics Red Book</u>

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# Drwg Topics



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SEVENTY-SECOND YEAR OF PUBLICATION

# Allergan Pharmweenticals 109 Almus S2 Ar-Ex Products Co. 46 Archer, B. F., & Co. 52, 53 Ayers: Laboratories 61-77 Esmes-Hind Pharmmenuticals 65 Becton-Dickinson 55-55 Bayle-Midway Division 95 Brown Laboratories 95-101 Espiral Laboratories 95-101 Espiral Laboratories 90-101 Espiral Laboratories 90-101 Espiral Laboratories 102 Esmund Pharmaceuticals 103 Esmund Pharmaceuticals 105 Columbia Medical Co. 105 Columbia Medical Co. 127 Doney Laboratories apposite 550 Eventio Products 3 Evenilo Products ................ avenno Fracticis 5 Ex-Lax, Inc. 180 Fulbr Pharmacoutical Co. 193 Ceigy Pharmacouticals 199-215 Cibson Greeting Cards opposite 240 Coodrich, B. F. & Co. Juside Back Cover Hankscraft Co. 227 Homer Highs Associates, Inc. 236 ives Laboratories 250-251 Leffery Martin 593 Homer friggs Associates, inc. less Laboratories 250.551 Jeffrey Martin 384 Knoll Pharmaceutical Co. 981 Lakeside Laboratories 265 Leha & Fink 571 Lippincott, J. B., Company 7 Missengill, S. E., Co. 287 Methose Co. 288 Methose Laboratories opposite 504 TeNeil Laboratories, Inc. 991 Methose Co., Inc. (Publications) 56 Nessea Corp 309 Nian Corp 316 Orbit Pharmaceutical Co., Inc. 326 Orbit Pharmaceutical Co., Inc. 326 Orbit Pharmaceutical Co., Inc. 326 Printing Corp. 340 Printing Corp. 340 Printing Corp. 340 Printing Corp. 350 Pfixer Laboratories 350 Pfix

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Prescription Department Requirements 4
Secretaries of Associations
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Herrison S. Frelier . . . . . . Publisher Walter Cousing, Jr. . . . . . . . . . . . Editor

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# Appendix 6

In re Complex DES Litigation, No. 830109 (Cal. Sup. Ct. Jul. 29, 1988)

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JUL 29 1988

DONALD W. DICKORSON, CANA

CALIFORNIA SUPERIOR COURT
CITY AND COUNTY OF SAN FRANCISCO
DEPARTMENT NUMBER EIGHTEEN

In re: COMPLEX DES LITIGATION.

NO. 830100

GENERAL ORDER NO. 29: ORDER APPROVING MATRIX

The court continues to address "the practical problems involved in deferring the market and determining the market share," as conceived in Sindell v. Abbott Laboratories (1980) 26 Cal.3d 588. General Order No. 26 attempted to define the market under the broad concepts of Sindell. On March 31, 1988, a unanimous Supreme Court affirmed prior General Orders of this court and gave specific guidance for the formulation of a market share equation. The case of Brown v. Superior Court (1988) 44 C.3d 1049 has resolved the issues which this court attempted to formulate inferentially from the language of Sindell.

The <u>Brown</u> opinion affirmed this court's ruling that the defendants could not be held strictly liable for the alleged defects in DES but only for their failure to warn of known or

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knowable side effects of the drug. The court further affirmed that neither breach of warranty nor fraud will lie in an action based on the market share theory. Finally, the Brown opinion affirmed the previous general order precluding join and several liability. The Supreme Court specifically held that under Sindell a defendant is only severally liable for its actual market share and concluded that the "... imposition of joint liability on defendants in a market share action would be inconsistent with this rationale." Brown, supra, p. 1075.

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The market share fashioned by this court must "... achieve as close an approximation as possible between a DES manufacturer's liability for damages and its individual responsibility for the injuries caused by the product it manufactured." Brown, supra, p. 1075.

The mandate of the Brown decision requires a reexamination of the application of General Order No. 26. It is clear from the evidence that the market shares developed in accord with the guidelines of General Order No. 26 result in inflated shares to many companies. Such an inflation was specifically and unequivocally rejected in Brown, supra.

". . . Each defendant would be held liable for the proportion of the judgment represented by its market share, and its overall liability for injuries caused by DES would approximate the injuries caused by the DES it manufactured. A DES manufacturer found liable under this approach would not be held responsible for injuries caused by another producer of the drug. The opinion acknowledged that only an approximation of a manufacturer's liability could be achieved by this procedure, but underlying our holding was a recognition that such a result was preferable to denying recovery altogether to plaintiffs injured by DES." Brown, supra, p. 1074. andres fragerica de la comThus, the court finds that it must modify its opinion of General Orders No. 26 and 27 and hold that the <u>Sindell</u> concept of likelihood as defined by <u>Brown</u> is to develop a matrix which attempts to ascribe only the actual market shares of the known companies in the DES market during the relevant times.

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The court finds, consistent with its holding in General Order No. 26, that Dr. Grabowski "... adopted a clear, reasonable, and comprehensive approach to establishing a reliable calculation for determining the market shares."

General Order No. 26, page 11. When examining Dr. Grabowski's methods in light of Brown, the only conclusion is that the court must adopt the matrix offered as Exhibit B to his Declaration introduced as Exhibit No. 20° to Phase Three, Market Share

Trial. The court expressly had adopted Dr. Grabowski's method because the determination of the denominator was a clear approach with a reality check that was reasonable.

Therefore, the court now finds that the matrix for a determination of a market share of an individual company in the relevant <u>Sindell</u> market shall be that set forth at Exhibit B to Dr. Grabowski's Declaration as explained at the Matrix Hearing on April 22, 1988.

The court finds that ascribing "nominal shares" to those companies without data does not comport with the mandate of Brown and the court finds that the assignment of nominal share would be of no assistance to a plaintiff in establishing a substantial share threshold.

Brown clearly points out that the market share theory is a carefully crafted balance between no remedy for a plaintiff

and the imposition of liability on defendants who are sued despite there being likelihood that their products could have caused a plaintiff's alleged injury. Brown, supra, at p. 1075. The principle is that Sindell does not guarantee recovery but assures recovery where a reasonable likelihood of the cause of harm can be established.

The court now orders that Exhibit B shall be determinative of market shares for the purpose of establishing liability in all cases in this complex litigation.

Liaison counsel for defendants shall cause a copy of the matrix to be served on all parties.

DATED: July 29, 1988

DANIEL M. HARLON

Judge of the Superior Court

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# Appendix 7

Selections from the New York DES Matrix

# NY SETTLEMENT SHARES 25 MG

"SJ" represents that the corresponding company has been granted summary judgment in the NY Market Share proceeding.

All shares are expressed as percentages.

HAACK LABS HAUSEY HANCE & WIHTE	EVRON	DEXTER	CIBA	CHASE	CARNEICK	BRYANT PHARM	BREWER	BREON	BOYLE	BOCH PINGER INGELHEI	BARRE	AYERSTLABORATORIE	AMFRE GRANT (EMONS	AMERICAN PHARM	AMERICAN HOME PROD	ABBOTT	
1.3669 0.1450 3.7094	0.1447	હ	8	0.2860	0.1205	0.6406	4.2639	2	0.1744	હ	0.1319	દ	8.3067	5.5222	હ	0.8067	1959
1.3669 0.2361 3.7094	0.1447	2	જ	0.2860	0.0675	0.6406	2.1864	જ	0.1643	ج	0.2833	હ	9,1019	5.5222	٤	0.5597	1960
1.2426 0.3057 3.3722	0.1315	స్	స్	0.2600	0.0265	0.5824		Σ.	0,0778	ည	0.3663	బ	7.7403	5.0202	స్	0.1210	1961
1.2426 0.2850 3.3722	0.1315	ফ	<u>ج</u>	0.2600	જ	0.5824		ၓ	0.0068	હ	0.4275	g	6.3583	5,0202	દ	હ	1962
1.2426 0.2222 2.2481	0.1315	ম	స్	0.2600	હ	0.5824		Ł		స్	0.4445	2	5.6276	5.0202	હ	હ	1963
0.8284 0.0785 1.1241	0.1315	S	ည	0.2600	స్	0.5824		2		ည	0.4712	Ş.	4.9654	5.0202	ည	స్	1964
0.4142	0.1315	હ	જ	0.1733	٤	0.5824		2		బ	0.4585	છ	3,4402	5.0202	ফ	હ	1965
0.1888	0.1315	હ	δū	0.0867	ফ	0.5824		ফ		જ	0.5149	જ	3.8318	5.0202	જ	હ	1966
0.5033	0.1315	ā	હ		હ	0.3882		٣		હ	0.5392	2	2,8454	5,0202	হ	હ	1967
0.6206	0.1315	ফ	হ		હ	0.1941		હ		ফ	0.5032	હ	1.5959	5,0202	গু	હ	1968
0,4905	0.1315	হ	જ		ফ			হ		દ	0.5074	હ	2.0129	5.0202	હ	ž	1969
0.2044	0.0876	ত	ည်		હ			હ		જ	0.5110	బ	4,3256	5,0202	g	દ	1970
	0,0438	ઈ	જ		S			Š.		2	0.6708	ফ	7.4664	5.0202	8	2	1971

# \* For all dosage sizes, shares derived from Periott 1 matrices, except for 100 mg, derived from Berck 100 mg matrix.

NY SETTLEMENT SHARES 25 MG

All shares are expressed as percentages. "SJ" represents that the corresponding company has been granted summary judgment in the NY Market Share proceeding.

								:	- 1	٠.		-											
REXALL	REID PROVIDENT	PREMO	PHYS'S DRUG & SUPPL	PERSON & COVEY	OTIS CLAPP	NORWICHEATON		MCHCX		MONTH (SINIII NA	MANOR DESCRIPTION OF THE PARTY	MALLINCX-RODT	LINCOLN	THY CHILD	LEDGRILE	<b>WANTI</b>	KREWERS URBAN	MAMAN	APY COM	IVES LABORATORY	HMATZ (FERNDALE)	-	
0.7714		0.8314	0.8018	0,7025	స్		0.7010	0.5933	0.003	2000	1 200	0.9859	0.1978	23.2730	હ	0.0672	0,3122	0.0748	0.0678	દ	0.1721	1959	
0.7595	2	0.9258	0.6018	0.4352	હ		0.2014	0.5430	٤	- C-	4 6400	11486		28.2838	బ	0.0699	0.3752	0.0724	0.1607	હ	0.3160	1960	
0.6006		0.9331	0.7289	0.3006	ຄ		0.1223	0.4232	Ų,	2000	in in	1.0931		31.6982	S.	0.0225	0.3914	0.0719	0.1956	స్	0.4377	1961	
0.5626	်	1.1117	0.7289	02111	ည			0.2179	ę		4 3253	0 8738		31.7605	હ	0.1112	0.2603	0.0587	0.1140	હ	0.3111	1962	
0.4812	ર્	1.3207	0.4859	0.1097	స్			0.0406	ų	0000	00000	0.5026	હ	29.2534	ফ	0.1505	0.0727	0.0535		ফ	0.0888	1963	
0.4756	Ę.	1.5074	0.2430		ន៍			Ş.	Ę	UCUC.U	0 200	0 20.0	ž	28.9453	స్	0.2004	0.0130	0.0351	~	ည		1964	
0.4109	હ	0.9974			55			چ	ž	2 &	7	0.0477	2	27,5400	55	0.2543		0.0250	હ	E		1965	
0.3776	છ	0.4774			55			Ş.	٤	٠ د	2		હ	33.4141	હ	0.4277		0.0222	হ	હ		1966	
0.2955	હ				స్			وي	٤	2 8	2		જ	36,1415	స్	0.4005		0.0175	હ	55		1967	
0.1925	હ				S			٤	, ų	2 &	2		હ	35.1788	ফ	0.1986		0.0121	2	હ		1968	
0.1137	ર્				દ			٠	2	2 &	2		જ	33.5739	స్			0.0081	હ	బ		1969	
0.0456	હ				જ			g	2 2		2		S	34.3265	હ્			0.0082	હ	S.		1970	
	2				ર્			Į.	2 6	2	2		S.	43.4455	જ			0.0107	స్	2		1971	

# NY SETTLEMENT SHARES 25 MG

"SJ" represents that the corresponding company has been granted summary judgment in the NY Market Share proceeding.

All shares are expressed as percentages.

establish.	
TOTAL	RITE-AID ROPER ROWELL SMITH, CARROLL, DUNH SMITH DORSEY (SANDO SQUIBB STANLEY SUCCESS TUTAG UPJOHN VITAFORE VITAFORE VITAFORE VICA. WEBSTER WESTWARD WYETH
66.5041 33.4960	1959 0.1319 0.3328 0.3328 0.6233 0.0594 0.3365 0.6577 0.2042 0.1574 0.7981 0.4151 SJ
71.2115 28.7885	1960 0.1133 0.3950 0.1133 0.3950 5.0066 0.8309 0.0650 0.3038 0.7006 0.2405 0.1524 0.7981 0.7981 0.3970 0.3970 0.3970
69.5441 30.4559	1961 SJ 0.0734 0.2889 7.6307 1.1836 0.0769 0.2851 0.2854 0.7255 0.4162 SJ
67.2453 32.7547	1962 S.J 0.2792 7.5925 1.7613 0.0811 0.3038 0.1887 0.3270 0.1236 0.7255 0.4749 S.J
60.4755 39.5245	1963 SJ 0.1826 0.1826 SJ 6.8379 2.2461 0.0822 0.2987 0.0450 0.1173 0.11144 0.7255 SJ SJ
\$6.0739 43.9261	1964 SJ 0.1336 SJ 6.7075 2.2490 0.0847 0.2984 SJ 0.1245 0.0797 0.4836 0.5222 SJ SJ
48.7850 51.2150	1965 SJ 0.1023 0.1023 1.8158 0.0583 0.2583 0.2589 0.0584 0.0584 0.0584 0.0584 0.0584 0.0584 0.0584 0.0584 0.0584
54,8319 45,1681	1966 SJ 0.0680 0.0680 6.4449 2.1831 0.0279 0.2471 SJ 0.1198 0.0512 0.6146 SJ SJ
56,5090 43,4910	1967 SJ 0.0412 0.0412 5.8386 3.3719 0.1105 0.0368 0.6403 SJ
53,0455 46,9545	1968 \$1,44386 0.1208 0.1208 0.0256 2.2
49.6314 50.3686	1969 SJ 3,3974 3,4096 0,0744 SJ 0,0893 0,0170 0,7855 SJ SJ
49.6092 50.3908	1970 SJ SJ 2.3314 2.1733 0.0477 SJ 0.0619 0.0114 0.4544 SJ SJ
59.9603 40.0397	1971 SJ SJ 1.6789 1.3506 0.0179 SJ 0.0405 0.0075 SJ SJ